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EXAMINER	
RAWLINGS, STEPHEN L	
ART UNIT	**PAPER NUMBER**
1643	

DATE MAILED: 04/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/848,948	HANASH ET AL.	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-14 and 16-34* is/are pending in the application.

4a) Of the above claim(s) *6-13 and 19-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,14,16-18 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 September 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed January 19, 2006, is acknowledged and has been entered. Claims 1, 14, and 34 have been amended.

2. Claims 1-4, 6-14, and 16-34 are pending in the application. Claims 6-13 and 19-33 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention or species of invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in paper filed January 21, 2003 (Paper No. 7).

3. Claims 1-4, 14, 16-18, and 34 are currently subject to examination.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Amendment

5. The amendment filed on January 19, 2006, is considered non-compliant because it fails to meet the requirements of 37 CFR § 1.121, as amended on June 30, 2003 (see *68 Fed. Reg. 38611*, Jun. 30, 2003). However, in order to advance prosecution, rather than mailing a Notice of Non-Compliant Amendment, Applicant is advised to correct the following deficiencies in replying to this Office action:

(a) The amendment to the claims is non-compliant because the status identifier of claim 33, which appears in parentheses, does not properly indicate that claim 33 has been withdrawn from further consideration; and

(b) The amendment to the specification is non-compliant because in order to amend the abstract, it is necessary to replace the sheet on which the abstract appears.

Briefly, the revised amendment practice now requires a listing of all claims beginning on a separate sheet. Each claim ever presented must be included in the listing of claims together with a single proper status identifier in parentheses. The permissible status identifiers include: "original", "currently amended", "canceled", "withdrawn", "previously presented", "new", "not entered", and "withdrawn – currently amended". The text of all pending claims, including withdrawn claims, must be presented. Markings to show only the changes made in the current amendment relative to the immediate prior version should be included with the text of all currently amended claims, including withdrawn claims that are amended. Added text must be shown by underlining the added text. Generally deleted text must be shown by strikethrough (e.g., ~~strikethrough~~); or if the strikethrough cannot be easily perceived, and for deletion of five or fewer characters, the deleted text may be marked by the inclusion of deleted text in double brackets (e.g., [[444]]). The text of "canceled" and "not entered" claims must not be presented; and consecutive "canceled" or "not entered" claims may be grouped together in one line (e.g., Claims 1-11 (canceled); Claims 51-62 (not entered)).

Only the corrected section(s) of the non-compliant amendment must be resubmitted (in its entirety), e.g., the entire "Amendments to the claims" section of applicant's amendment must be re-submitted. 37 CFR § 1.121(h).

For further explanation of the amendment format required by 37 CFR § 1.121, see MPEP § 714.

Grounds of Rejection Withdrawn

6. Unless specifically reiterated below, Applicant's amendment filed January 19, 2006, has obviated or rendered moot the grounds of rejection set forth in the Office action mailed September 20, 2005.

For additional clarity, it is noted that Applicant has remarked the amendment to the claims has obviated the rejection of claims 1 and 2 under 35 U.S.C. 102(b), as being anticipated by Celis et al. (J. Urol. 1996 Jun; 155 (6): 2105-2112), since the amended claims are directed to a method comprising detecting S100-A7 in blood or a fraction thereof, and Celis et al. teaches the

antigen was not detected in the serum of the patients; see page 10 of the amendment. While it is agreed that Celis et al. teaches the antigen was not detected in the serum of the patients, it is also noted that Celis et al. does not teach or fairly suggest diagnosing lung cancer by detecting the antigen in any bodily fluid, such as the urine or the blood. It is for these reasons that the rejection of claims 3, 14, 16-18, and 34 35 U.S.C. 103(a), as being unpatentable over Celis et al. (J. Urol. 1996 Jun; 155 (6): 2105-2112) in view of BIO-RAD Life Sciences Research Products Price List Q (March 1991), has also been withdrawn.

Grounds of Objection Maintained

Specification

7. The objection to the abstract of the disclosure is maintained. As explained in the preceding Office action, because the abstract is entitled "Abstract of the Invention", as opposed to "Abstract" or "Abstract of the Disclosure", it is improper. See MPEP § 608.01(b).

It is noted that Applicant has made a *bona fide* attempt to remedy this deficiency by amending the title of the abstract; however, as explained above, the amendment to the specification (i.e., the abstract) is not compliant with the requirements set forth under 37 C.F.R. 1.121. It is not sufficient to merely amend the title, as in order to amend the abstract it is instead necessary to replace the entirety of the sheet on which the prior abstract appears. Accordingly, Applicant should submit a replacement sheet on which the amended abstract appears, showing how the title of the abstract has been changed relative to its immediate prior version, which was filed as part of the original application on May 4, 2001.

Correction is required.

Grounds of Rejection Maintained

Claim Rejections - 35 USC § 112

8. Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

At pages 11 and 12 of the amendment filed January 19, 2006, Applicant has traversed this ground of rejection.

Applicant's arguments have been carefully considered but not found persuasive for the following reasons:

Claims 1-4, as amended, are directed to a method for diagnosing lung cancer in a subject comprising detecting a S100-A7 protein in a sample of blood or a blood fraction derived from a subject and comparing the level of the protein in the subject's sample to the level of protein derived from a control sample; wherein an increase in the level of the protein in the subject's sample, as compared to the level of the protein in the control, indicates the subject is afflicted with lung cancer.

As explained in the preceding Office action, the prior art (e.g., Celis et al.; cited *supra*) teaches a process for diagnosing bladder cancer in a subject comprising detecting S100-A7 in a sample of urine acquired from a subject using an immunoassay and comparing the level of the protein to the level of the protein in a control sample, wherein a relative increase in the level of the protein in the sample of urine is an indicator that the subject of a subject with bladder cancer.

Although Celis et al. discloses a relative abundance of S100-A7 in the urine of patients with bladder cancer, Celis et al. teaches the protein could not be detected in serum (e.g., page 2109, column 1).

The specification provides very little guidance, direction, and exemplification with regard to the claimed invention. At page 10, lines 13-15, the specification teaches, "S100-A7 and S100-A8 proteins were shown to be secreted by breast cancer cells, which provide the basis for diagnostic and prognostic assays for breast cancer" and at page 17, lines 16 and 17, the specification discloses, "mass spectrometry identified S100A7 as a secreted protein in breast cancer". However, apart from this very little guidance and direction, there is none other that would enable the artisan to practice the claimed invention and moreover, the use of the claimed invention to diagnose any type of cancer, including breast cancer has not been exemplified.

As further explained in the preceding Office action, Celis et al. provides factual evidence that the skilled artisan cannot predict which types of cancer cells secrete S100-A7 into the various different biological fluids (e.g., serum, plasma, urine, saliva, cerebrospinal fluid, feces, etc.). More particularly, as evidenced by Celis et al., the skilled artisan cannot predict whether

lung cancer cells secrete S100-A7, and moreover whether lung cancer cells secrete the protein into the blood, or some fraction thereof, such as the serum.

Again, the specification provides insufficient guidance, direction, and exemplification to remedy the insufficiencies of the prior art to enable the skilled artisan to use the claimed invention without undue and/or unreasonable experimentation. This is because it would be first be necessary to determine whether lung cancer cells secrete detectable quantities of S100-A7 into the blood or a fraction thereof (e.g., serum), and then whether or not the levels of the protein in those fluids is substantially different from the levels found in the same fluids acquired from unaffected control individuals, such that a difference would provide an indication of a subject with cancer. In other words, it is not evident, even given the instant disclosure, whether the invention can be practiced to achieve the claimed objective.

In conclusion, upon careful consideration of the factors used to determine whether undue experimentation is required, in accordance with the Federal Circuit decision of *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988), the amount of guidance, direction, and exemplification disclosed in the specification, as filed, would not be sufficient to have enabled the skilled artisan to use the claimed invention at the time the application was filed without undue and/or unreasonable experimentation.

Claim Rejections - 35 USC § 102

9. The rejection of claim 34 under 35 U.S.C. 102(a), as being anticipated by Newton et al. (*J. Immunol.* 1998; **160**: 1427-1435), is maintained.

At page 9 of the amendment filed January 19, 2006, Applicant has traversed this ground of rejection.

Applicant's argument has been carefully considered but not found persuasive for the following reasons:

Applicant has remarked that the amendment to claim 34 has obviated this ground of rejection, since the amended claim is directed to a kit comprising an antibody that is "specific for detecting S100-A7 or S100-A8". Applicant has contended that the prior art does not teach an antibody having the required specificity.

In response, the prior teaches a kit comprising a monoclonal antibody (i.e., 27E10), which is specific for the MRP-8/14 heterodimer; see, e.g., page 1428, column 1. The antibody disclosed by the prior art is not specific for detecting S100-A7. Nonetheless, as the record shows, the MRP-8/14 heterodimer is composed of S100-A8 (i.e., MRP-8) and S100-A9 (i.e., MRP-14). An antibody that is specific for the MRP-8/14 heterodimer is "specific for detecting S100-A7 or S100-A8". For clarity, claim 34 does not require the kit to bind exclusively, or even specifically to S100-A8; rather it the antibody is only required to be specific *for detecting* S100-A8. For these reasons, contrary to Applicant's contention, the prior art anticipates the claimed invention.

Double Patenting

10. The provisional rejection of claim 34 under the judicially created doctrine of obviousness-type double patenting, as being unpatentable over claims 13-15 of copending U.S. Patent Application No. 10/461,424 in view of BIO-RAD Life Sciences Research Products Price List Q (March 1991; pages 190 and 233-240), is maintained.

This is a provisional obviousness-type double patenting rejection.

At page 10 of the amendment filed January 19, 2006, Applicant has stated that a terminal disclaimer was submitted together with the amendment; however, no such terminal disclaimer has been found, so it appears that either the terminal disclaimer was not filed or it has been misplaced or misfiled.

New Grounds of Objection

Claim Objections

11. Claims 1-4 are objected to for the following reason:

Claims 1-4 have been interpreted as being drawn in the alternative to the subject matter of non-elected species of inventions.

Applicant is reminded that the elected species of invention is a method for diagnosing lung cancer; accordingly, claims 1-4, as amended, are directed to the non-elected species of invention, wherein the cancer that is diagnosed is breast or colon cancer.

Appropriate correction is required.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-4 are indefinite for the following reason:

The body of the claim 1 recites "wherein an increase in the level of S100-A7 in the subject's sample as compared to a control sample is an indicator of a subject with breast cancer, lung cancer or colon cancer", but the intended use of the claimed process, as recited in the preamble, is to diagnose "cancer". It is unclear whether the subject matter that is regarded as the invention is a process for diagnosing cancer, or a process for diagnosing lung cancer. Cancer is a genus, whereas lung cancer is a species. Because of the difference in scope of the terminology used in the preamble and the body of the claim, the claim fails to delineate the metes and bounds of the subject matter that is regarded as the invention with the requisite degree of clarity and particularity to permit the skilled artisan to know or determine infringing subject matter and thereby satisfy the requirement set forth under 35 U.S.C. § 112, second paragraph.

This issue may be remedied by amending claim 1 to recite, "[a] method for diagnosis of lung cancer".

14. Claims 1-3, 14, 16-18, and 34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a "new matter" rejection.

Claims 1, 14, and 34 recite, "a sample of blood or a blood fraction".

It appears that Applicant has not pointed to any particular disclosure in the specification, including the claims, as originally filed, which Applicant believes provide the necessary written support for the claim language. MPEP § 2163 states, "when filing an amendment an applicant should show support in the original disclosure for new or amended claims". See MPEP § 714.02 and § 2163.06. Nevertheless, as MPEP § 2163 further states: "The examiner has the initial burden of presenting evidence or reasoning to explain why persons skilled in the art would not recognize in the original disclosure a description of the invention defined by the claims. See Wertheim, 541 F.2d at 263, 191 USPQ at 97".

The specification, including the claims, as originally filed, provides written support for detecting any one or more of the disclosed S100 proteins in a bodily fluid, or more particularly in the serum. The serum is but a mere fraction of the blood; and a bodily fluid is not necessarily blood or a fraction thereof.

Applicant is reminded that it cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. See *In re Smith*, 173 USPQ 679, 683 (CCPA 1972).

For these reasons, the specification, as filed, and more particularly the disclosures describing the detection of the protein in a bodily fluid or in the serum do not provide proper or sufficient written support for the language of the present claims. As such, it appears the amendment to the claims has introduced new matter and thereby violated the written description requirement set forth under 35 U.S.C. 112, first paragraph.

This issue might be remedied if Applicant were to point to particular disclosures in the specification, including the claims, as originally filed, which are believed to provide the necessary written support.

15. Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a "written description" rejection.

The considerations that are made in determining whether a claimed invention is supported by an adequate written description are outlined by the published Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, para. 1, ``Written Description'' Requirement (Federal Register; Vol. 66, No. 4, January 5, 2001). A copy of this publication can be viewed or acquired on the Internet at the following address: <http://www.gpoaccess.gov/>.

These guidelines state that rejection of a claim for lack of written description, where the claim recites the language of an original claim should be rare. Nevertheless, these guidelines further state, "the issue of a lack of written description may arise even for an original claim when an aspect of the claimed invention has not been described with sufficient particularity such that one skilled in the art would recognize that the applicant has possession of the claimed invention" (*Id.* at 1105). The "Guidelines" continue:

> The claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the art or known to one of ordinary skill in the art. This problem may arise where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process.

With further regard to the proposition that, as *original* claims, the claims themselves provide *in haec verba* support sufficient to satisfy the written description requirement, the Federal Circuit has explained that *in ipsis verbis* support for the claims in the specification does not *per se* establish compliance with the written description requirement:

> Even if a claim is supported by the specification, the language of the specification, to the extent possible, must describe the claimed invention so that one skilled in the art can recognize what is claimed. The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). *See also:* University of Rochester v. G.D. Searle & Co., 69 USPQ2d 1886 1892 (CA FC 2004).

Thus, an original claim may provide written description for itself, but it must still be an adequate written description, *which establishes that the inventor was in possession of the invention.*

In this instance, the claims, as amended, are directed to a method for diagnosing lung cancer by detecting in the blood or a fraction thereof (claims 1-3), such as the serum (claim 4), S100-A7. As explained the rejection above, it appears the amendment of claims 1-3 to recite a sample of blood or a blood fraction" violates the written description requirement by introducing new matter; claim 4, however, has not been rejected for this reason, as it specifically recites the sample is a sample of serum. Even so, while there may be *in ipsis verbis* support for the language of the claim 4 in the specification, as explained in the paragraphs above, that does not *per se* establish compliance with the written description requirement.

As explained in the above rejection of claims 1-4, as failing to satisfy the enablement requirement, the specification describes very little of the claimed invention. At page 10, lines 13-15, the specification teaches, "S100-A7 and S100-A8 proteins were shown to be secreted by breast cancer cells, which provide the basis for diagnostic and prognostic assays for breast cancer"; and at page 17, lines 16 and 17, the specification discloses, "mass spectrometry identified S100A7 as a secreted protein in breast cancer".

These disclosures would not reasonably convey to the skilled artisan that Applicant had possession of the claimed invention at the time the application was filed, as there is no teaching or disclosure of any factual evidence that might reasonably suggest the presence of S100-A7 in the serum, or any other fraction of the blood, of patients diagnosed with lung cancer. Moreover, the disclosure that S100-A7 was found secreted into the culture medium from cultured breast cancer cells (see, e.g., the specification, page 17, lines 6-19) does not constitute a reasonable showing that the protein is secreted into the blood, or more particularly the serum by lung cancer cells *in vivo*. Applicant is reminded that Celis et al. (cited *supra*) found S100-A7 was secreted into the *urine* of patients afflicted with *bladder* squamous cell carcinomas, but not into the patients' sera; see entire document (e.g., the abstract).

"[G]eneralized language may not suffice if it does not convey the detailed identity of an invention." *University of Rochester v. G.D. Searle Co.*, 69 USPQ2d 1886 1892 (CAFC 2004).

Furthermore, the Federal Circuit has decided that a patentee of a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from species other than those specifically enumerated. See *Noelle v. Lederman*, 69 USPQ2d 1508 1514 (CA FC 2004) (citing *Enzo Biochem II*, 323 F.3d at 965; *Regents*, 119 F.3d at 1568). In this instance, there is no language that adequately describes with the requisite degree of particularity necessary to satisfy the written description requirement the presence of S100-A7 in the serum, or any other fraction of the blood, of patients afflicted with lung cancer. Absent such necessary description, the disclosure would not reasonably convey to the skilled artisan that Applicant had possession of the claimed invention at the time the application was filed.

Although, at the invitation provided by the instant disclosure, the skilled artisan might later determine that S100-A7 is secreted into the serum, or another fraction of the blood, in patients afflicted with lung cancer, so that perhaps the claimed invention could be developed for use in the clinical setting, it is duly noted that the written description provision of 35 U.S.C § 112 is severable from its enablement provision; and adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it.

> The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the "written description" inquiry, *whatever is now claimed.*

Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (CAFC 1991). See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993); *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (CAFC 1991); *University of Rochester v. G.D. Searle Co.*, 69 USPQ2d 1886 1892 (CAFC 2004).

Conclusion

16. No claim is allowed.

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1643

slr
March 29, 2006